

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

LYNN OXENBERG and
RONALD LEWIS

Plaintiffs,

v.

ALEX AZAR,

Defendant.

Case No. 2:20-cv-00738-CMR

**DECLARATION OF JAMES C. PISTORINO IN SUPPORT
OF PLAINTIFFS' REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT
AND OPPOSITION TO CROSS-MOTION FOR SUMMARY JUDGMENT**

James C. Pistorino, Esq., being duly sworn, deposes and say as follows:

1. I am an attorney with the law firm Parrish Law Offices. I represent the Plaintiffs in the above-captioned action. I submit this Declaration in further support of Plaintiffs' Motion for Summary Judgment and in Opposition to Defendant's Cross-Motion for Summary Judgment.

2. Attached hereto as Exhibit I are true and correct copies of status reports filed by Defendant Alex Azar in *American Hospital Association v. Azar*, Case No. 14-cv-851 (D.D.C.) (pending) filed on March 23, 2020 and December 21, 2018.

3. Attached hereto as Exhibit J is a true and correct copy of excerpts from a brief filed on April 21, 2020, in *Lewis v. Azar*, Case No. 18-cv-2929 (D.D.C.) (pending).

4. Attached hereto as Exhibit K is a true and correct copy of excerpts from M. BIGELOW, "A TREATISE ON THE LAW OF ESTOPPEL OR OF INCONTESTABLE RIGHTS", Chap. 2, § 2 (6th ed. 1913).

5. Attached hereto as Exhibit L is a true and correct copy of a decision issued by Administrative Law Judge Scott Anderson on May 28, 2019 in *In re: LCD Complaint*; Docket No. C-19-396.

6. Attached hereto as Exhibit M is a true and correct copy of excerpts from the CMS Financial Report for 2018.

7. I declare under penalty of perjury under the laws of the United States of America that the foregoing statements are true and correct to the best of my knowledge, information and belief.

Dated: May 4, 2020

/s/ James C. Pistorino

James C. Pistorino, Esq.

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EXHIBIT I

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs,

v.

ALEX. M. AZAR, in his official capacity as
Secretary of Health and Human Services,

Defendant.

Civil Action No. 14-cv-00851 (JEB)

DEFENDANT'S STATUS REPORT

Pursuant to the Court's 2018 Order (ECF No. 89), the Secretary of Health and Human Services ("HHS") provides this status report to inform the Court that HHS remains on track to meet the reduction targets set forth in the Court's Order. Attached to this status report are statistics concerning, *inter alia*, the backlog of appeals at the Office of Medicare Hearings and Appeals ("OMHA") as of the end of the first quarter of FY 2020. *See* Medicare Appeals Dashboard, Exhibit 1. By the end of the first quarter of 2020, a total of 268,115 appeals remain pending at OMHA, which is a 37% reduction from the starting number of appeals identified in the Court's 2018 Order (426,594 appeals).

Dated: March 25, 2020

Respectfully submitted,

JOSEPH H. HUNT
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Federal Programs Branch

/s/ Nicholas Cartier
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Medicare Appeals Dashboard

Reporting Period: Through Quarter 1 of FY 2020 (December 31, 2019)

(Data in Appeals)

Level 3 - OMHA	Fiscal Year						Most Recent 6 Quarters					
							FY 2020	FY 2019				FY 2018
	FY 2020	FY 2019	FY 2018	FY 2017	FY 2016	FY 2015	Qtr.1	Qtr.4	Qtr.3	Qtr.2	Qtr.1	Qtr.4
Beginning Workload Balance	292,517	417,198	578,683	675,530	886,418	767,422	292,517	318,254	343,658	379,831	417,198	483,401
Receipts	7,560	43,887	62,762	112,933	184,240	240,360	7,560	11,744	7,989	10,195	13,959	17,132
<i>RAC</i>	242	485	774	13,782	35,527	47,929	242	181	97	76	131	113
<i>non-RAC</i>	7,318	43,402	61,988	99,151	148,713	192,431	7,318	11,563	7,892	10,119	13,828	17,019
Appeals Removed	(31,962)	(168,568)	(224,247)	(209,780)	(395,128)	(121,364)	(31,962)	(37,481)	(33,393)	(46,368)	(51,326)	(83,335)
<i>OMHA Dispositions</i>	(28,280)	(119,848)	(92,113)	(82,240)	(87,123)	(78,881)	(28,280)	(26,301)	(29,570)	(31,490)	(32,487)	(24,146)
<i>RAC</i>	(3,880)	(15,708)	(24,690)	(26,054)	(33,511)	(15,586)	(3,880)	(3,707)	(4,434)	(4,021)	(3,546)	(5,293)
<i>non-RAC</i>	(24,400)	(104,140)	(67,423)	(56,186)	(53,612)	(63,295)	(24,400)	(22,594)	(25,136)	(27,469)	(28,941)	(18,853)
<i>SCF (non-add) ⁷</i>	(16)	(14,021)	(57,097)	(3,208)			(16)	(129)	(4,243)	(2,860)	(6,789)	(4,585)
<i>Appeals combined for efficiency</i>	(3,020)	(25,339)	(29,248)	(10,426)	(59,375)		(3,020)	(3,796)	215	(8,065)	(13,693)	(29,248)
<i>QIC demo - remands for resolution</i>	(656)	(14,243)	(20,175)	(22,505)	(2,387)		(656)	(4,168)	(3,176)	(5,888)	(1,011)	(3,996)
<i>Serial Claims Initiative</i>	0	(3,076)	(2,574)				0	(961)	(579)	(746)	(790)	(432)
<i>Low Volume Appeals</i>	(1)	(5,784)	(20,817)				(1)	(2,231)	(282)	(174)	(3,097)	(20,817)
<i>Hospital Settlements</i>	(5)	(278)	(2,223)	(91,401)	(246,243)	(42,483)	(5)	(24)	(1)	(5)	(248)	(111)
<i>Inpatient Rehab Facility Settlement (non-add)</i>	(460)	(6)					(460)	(6)				
Net Pending Receipt Increase / (Decrease)	(24,402)	(124,681)	(161,485)	(96,847)	(210,888)	118,996	(24,402)	(25,737)	(25,404)	(36,173)	(37,367)	(66,203)
Ending Workload (pending appeals)	268,115	292,517	417,198	578,683	675,530	886,418	268,115	292,517	318,254	343,658	379,831	417,198

1/ FY20 Qtr.1 includes the majority of appeals received through December 31, 2019.

2/ Receipts and dispositions have been updated due to appeal adjustments such as combinations, deletions, and/or corrections.

3/ Receipts exclude reopened appeals but include appeals involved in CMS Hospital Settlements.

4/ The number of appeals adjudicated each fiscal year reflects receipts from multiple fiscal years.

5/ Dispositions exclude remands.

6/ OMHA Dispositions reflect appeals removed by all types of adjudicators.

7/ Starting in FY19, appeals removed through Settlement Conference Facilitation (SCF) are included in OMHA Dispositions at a 1:1 ratio. Appeals combined for efficiency have been restated for FY19 due to SCF data adjustments.

8/ FY15 through FY18 reflect changes in methodology to include combined appeals. Discrepancies between Level 2 and Level 3 RAC receipts are largely attributable to these changes in methodology.

9/ Appeals combined for efficiency result in one disposition for a group of combined appeals. This line accounts for the remainder of received appeals that were combined into single appeals within disposition counts.

10/ Initiative dispositions not reflected separately within the table are counted in "OMHA Dispositions" (as 1 disposition if multiple appeals were combined), and "Received appeals combined for efficiency" (remainder of groups of appeals combined for efficient disposition).

11/ OMHA combines appeals to improve the efficiency of our ALJs. This includes a large number of Lincare dismissals. In FY18 OMHA dismissed 8,382 Lincare appeals. That number rose to 27,607 Lincare appeals in FY19.

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs,

v.

ALEX. M. AZAR, in his official capacity as
Secretary of Health and Human Services,

Defendant.

Civil Action No. 14-cv-00851 (JEB)

DEFENDANT'S STATUS REPORT

Pursuant to the Court's November 1, 2018 Order (ECF No. 89), the Secretary of Health and Human Services ("HHS") provides this status report to inform the Court that HHS remains on track to meet the reduction targets in the Court's November 1 Order. Attached to this status report are statistics concerning, *inter alia*, the backlog of appeals at the Office of Medicare Hearings and Appeals ("OMHA"), updated to reflect data received during the fourth quarter of FY 2018. *See* Medicare Appeals Dashboard, Exhibit 1. As this attachment reflects, there were 417,198 appeals pending at the end of the fourth quarter, and there were only 774 RAC-related appeals that reached OMHA during FY 2018.

Dated: December 21, 2018

Respectfully submitted,

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Of Counsel:

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Copy of Medicare Appeals Dashboard FY 2018 Q4 Filing

Medicare Appeals Dashboard

Reporting Period: Through Quarter 4 FY 2018
(Data in Appeals)

Level 3 - OMHA	Fiscal Year							Most Recent 6 Quarters					
								FY 2018			FY 2017		
	FY 2018	FY 2017	FY 2016	FY 2015	FY 2014	FY 2013	FY 2012	Qtr 4	Qtr 3	Qtr 2	Qtr 1	Qtr 4	Qtr 3
Beginning Workload Balance	578,683	675,530	886,418	767,422	380,696	75,922	20,382	483,401	494,490	518,475	578,683	604,370	657,728
Receipts	62,762	112,933	184,240	240,360	474,063	384,151	117,068	17,132	17,752	10,985	16,893	26,213	27,186
RAC	774	13,782	35,527	47,929	239,383	193,159	30,331	113	150	127	384	1,360	2,097
non-RAC	61,988	99,151	148,713	192,431	234,680	190,992	86,737	17,019	17,602	10,858	16,509	24,853	25,089
Appeals Removed	(224,247)	(209,780)	(395,128)	(121,364)	(87,337)	(79,377)	(61,528)	(83,335)	(28,841)	(34,970)	(77,101)	(51,900)	(80,544)
OMHA Dispositions	(92,113)	(82,240)	(83,765)	(78,390)	(87,337)	(79,377)	(61,528)	(24,146)	(24,278)	(23,345)	(20,344)	(20,793)	(20,579)
RAC	(24,690)	(26,054)	(31,042)	(15,225)	(28,104)	(17,739)	(12,357)	(5,293)	(5,895)	(6,880)	(6,622)	(6,453)	(4,622)
non-RAC	(67,423)	(56,186)	(52,723)	(63,165)	(59,233)	(61,638)	(49,171)	(18,853)	(18,383)	(16,465)	(13,722)	(14,340)	(15,957)
Appeals combined for efficiency	(37,743)	(10,426)	(56,821)	(3,220)				(37,743)				(10,426)	
Settlement conference facilitation - incl. States	(57,097)	(3,208)	(5,912)	(2,192)				(4,585)	(1,083)	(5,200)	(46,229)	(884)	(2,324)
QIC demo - remands for resolution	(20,175)	(22,505)	(2,387)					(3,996)	(2,623)	(3,082)	(10,474)	(5,622)	(3,497)
Serial Claims Initiative	(2,574)							(432)	(510)	(1,578)	(54)		
Low Volume Appeals	(12,322)							(12,322)					
CMS Hospital Settlements	(2,223)	(91,401)	(246,243)	(37,562)				(111)	(347)	(1,765)	0	(14,175)	(54,144)
Net Pending Receipt Increase / (Decrease)	(161,485)	(96,847)	(210,888)	118,996	386,726	304,774	55,540	(66,203)	(11,089)	(23,985)	(60,208)	(25,687)	(53,358)
Ending Workload (pending appeals)	417,198	578,683	675,530	886,418	767,422	380,696	75,922	417,198	483,401	494,490	518,475	578,683	604,370

1/ Receipts exclude reopened appeals but include appeals involved in CMS Hospital Settlements.

2/ The number of appeals adjudicated each fiscal year reflects receipts from multiple fiscal years.

3/ Dispositions exclude remands.

4/ OMHA Dispositions reflect appeals removed by all types of adjudicators, and by all initiatives except those listed in the table above.

5/ Some FY14 dispositions are attributable to Scooter Store dismissals.

6/ FY14 through FY18 reflect changes in methodology to include combined appeals.

7/ FY18 Qtr 4 includes the majority of appeals received through September 30, 2018.

8/ Receipts and dispositions have been updated due to appeal adjustments such as combinations, deletions, and/or corrections.

9/ Appeals combined for efficiency result in one disposition for a group of combined appeals. This line accounts for the remainder of received appeals that were combined into single appeals within disposition counts.

10/ Initiative dispositions not reflected separately within the table are counted in "OMHA Dispositions" (as 1 disposition if multiple appeals were combined), and "Received appeals combined for efficiency" (remainder of groups of appeals combined for efficient disposition).

EXHIBIT J

Case No. 18-cv-2929 (RBW)

DEFENDANT'S MEMORANDUM IN OPPOSITION TO CLASS CERTIFICATION

Third, and finally, the Secretary turns to Rule 23. Plaintiffs must “affirmatively demonstrate” their compliance with that rule to merit class certification. *Comcast Corp. v. Behrend*, 569 U.S. 27, 33 (2013). They have not done so here, principally because a class of twelve does not satisfy the numerosity requirement of Rule 23(a)(1). For that reason, and others discussed below, class certification should be denied.

I. Neither plaintiff should be permitted to litigate this case on the merits.

The Court can resolve this case without addressing plaintiffs’ motion for class certification, and it should do so. The Court has jurisdiction over the claim presented by Ms. Lewis, but the only issue that she raises is *res judicata* in her favor. Although Ms. Lewis would prefer to evade the preclusive effect of her judgment in the District of Massachusetts, and litigate this case a second time, the Court has the clear authority to address issue preclusion *sua sponte*. The Court need not entertain repetitious litigation on the merits when an earlier judgment establishes a clear entitlement to relief here. And as the Secretary has explained in his pending motion to dismiss, the Court lacks subject matter jurisdiction over the two claims presented by Mr. Sargent, because both fall short of the Medicare Act’s jurisdictional amount in controversy.

A. Carol Lewis has won a judgment on this issue; she is therefore entitled to preclusion and payment of her claim, but not to fully litigate a second case.

Ms. Lewis has already litigated to final judgment against the Secretary the issue of whether her continuous glucose monitor is durable medical equipment under the Medicare statute and regulations. She won. *Lewis v. Azar*, 308 F. Supp. 3d 574, 579 (D. Mass. 2018). But now she would avoid the judgment in her favor and persuade this Court to repeat the exercise. “Once a party has fought out a matter in litigation with the other party, [s]he cannot later renew that duel.” *Comm’r v. Sunnen*, 333 U.S. 591, 598 (1948). Ms. Lewis is entitled to the preclusive effect of her earlier victory; she has no right to pretend that it never happened. This Court should

enter judgment in her favor on the grounds of *res judicata* and remand her case to the Secretary, so that he can pay her claim. It should not entertain “repetitious litigation involving . . . the same issue[]” already resolved between these parties. *I.A.M. Nat’l Pension Fund v. Indus. Gear Mfg. Co.*, 723 F.2d 944, 946 (D.C. Cir. 1983).

“The preclusive effect of a judgment is defined by claim preclusion and issue preclusion, which are collectively referred to as ‘res judicata.’” *Taylor v. Sturgell*, 553 U.S. 880, 892 (2008); *accord NextWave Pers. Commc’ns Inc. v. FCC*, 254 F.3d 130, 142 (D.C. Cir. 2001) (quoting *I.A.M.*, 723 F.2d at 946). “The objective of the doctrine of issue preclusion (also known as collateral estoppel) is judicial finality; it ‘fulfills the purpose for which civil courts had been established, the conclusive resolution of disputes within their jurisdiction.’” *Yamaha Corp. of Am. v. United States*, 961 F.2d 245, 254 (D.C. Cir. 1992) (quoting *Kremer v. Chemical Constr. Corp.*, 456 U.S. 461, 467 n.6 (1982)); *accord Montana v. United States*, 440 U.S. 147, 153 (1979); *Consol. Edison Co. v. Bodman*, 449 F.3d 1254, 1258 (D.C. Cir. 2006) (quoting *Yamaha*).

“Issue preclusion . . . bars ‘successive litigation of an issue of fact or law actually litigated and resolved in a valid court determination essential to the prior judgment. . . .’” *Taylor*, 553 U.S. at 892 (quoting *New Hampshire v. Maine*, 532 U.S. 742, 748–49 (2001)); *accord Yamaha*, 961 F.2d at 254 (“The Supreme Court has defined issue preclusion to mean that ‘once a court has decided an issue of fact or law necessary to its judgment, that decision’” usually “‘preclude[s] relitigation of the issue in a suit on a different cause of action involving a party to the first case.’” (quoting *Allen v. McCurry*, 449 U.S. 90, 94 (1980)); *Cotton v. Heyman*, 63 F.3d 1115, 1119 (D.C. Cir. 1995) (“Generally, issue preclusion bars the relitigation of specific issues decided in a prior proceeding between the same parties.”); *McLaughlin v. Bradlee*, 803 F.2d 1197, 1201 (D.C. Cir. 1986) (quoting *Allen*). As the Second Restatement puts it, “When an

issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim.” Restatement (Second) of Judgments § 27 (1982); *accord Amador County, Cal. v. Salazar*, 640 F.3d 373, 384 (D.C. Cir. 2011); *Consol. Edison*, 449 F.3d at 1258; *Fogg v. Ashcroft*, 254 F.3d 103, 111 (D.C. Cir. 2001) (all quoting Second Restatement).

Under the D.C. Circuit’s three-part test “for establishing the preclusive effect of a prior holding,” *Yamaha*, 961 F.2d at 254, Ms. Lewis’s previous judgment clearly entitles her to prevail here. “First, the same issue now being raised”—the question of whether continuous glucose monitors are durable medical equipment under the Medicare statute and regulations—was “contested by the parties and submitted for judicial determination in the prior case.” *Id.*; *see Lewis*, 308 F. Supp. 3d at 576 (exercising “judicial review” over the Secretary’s finding that a “CGM was not covered under the Durable Medical Equipment (‘DME’) Medicare benefit”). “Second, the issue must have been actually and necessarily determined by a court of competent jurisdiction in the prior case.” *Yamaha*, 961 F.2d at 254. It was. *Lewis*, 308 F. Supp. 3d at 579 (holding that the Secretary’s interpretation “constituted legal error”). “Third, preclusion in the second case must not work a basic unfairness to the party bound by the first determination.” *Yamaha*, 961 F.2d at 254 (“An example of such unfairness would be when the losing party lacked any incentive to litigate the point in the first [case], but the stakes of the second [case] are of a vastly greater magnitude.”) The Secretary lost the first case, and does not suggest that entry of judgment for Ms. Lewis on the grounds of issue preclusion would be unfair in any way.

The issue in this case is plainly *res judicata* between Ms. Lewis and the Secretary. The only question is whether Ms. Lewis can avoid the preclusive effect of her first judgment by refusing to raise it here. This Court need not—and should not—permit her to do so.

“It is a sound and important policy in the administration of justice that what has already been done and determined not be redone and redetermined unnecessarily.” *Texaco, Inc. v. Hickel*, 437 F.2d 636, 646 (D.C. Cir. 1970). “[W]hile *res judicata* exists in part to shield parties from duplicative and vexatious litigation, the interests that courts protect are also often their own—or, more precisely, those of society.” *Stanton v. D.C. Court of Appeals*, 127 F.3d 72, 77 (D.C. Cir. 1997); *Allen*, 449 U.S. at 94 (“As this Court and other courts have often recognized, . . . collateral estoppel relieve[s] parties of the cost and vexation of multiple lawsuits, conserve[s] judicial resources, and, by preventing inconsistent decisions, encourage[s] reliance on adjudication.”); *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 326 (1979) (“Collateral estoppel . . . has the dual purpose of protecting litigants from the burden of relitigating an identical issue with the same party . . . and of promoting judicial economy by preventing needless litigation.”); see *Taylor*, 553 U.S. at 892; *Montana*, 440 U.S. at 153–54. “Courts today are having difficulty giving a litigant one day in court. To allow that litigant a second day is a luxury that cannot be afforded.” *Stanton*, 127 F.3d at 77 (quoting *National Treasury Employees Union v. IRS*, 765 F.2d 1174, 1177 (D.C. Cir. 1985)); see also *Federated Department Stores, Inc. v. Moitie*, 452 U.S. 394, 401 (1981) (explaining that “today’s crowded dockets” make principles of preclusion “even more compelling”).

“As *res judicata* belongs to courts as well as to litigants, even a *party’s* forfeiture of the right to assert it . . . does not destroy a *court’s* ability to consider the issue *sua sponte*.” *Stanton*, 127 F.3d at 77 (emphases in original). As the D.C. Circuit has explained, a “district court may

apply res judicata upon taking judicial notice of [the] parties' previous case." *Tinsley v. Equifax Credit Info. Servs.*, 1999 WL 506720, at *1 (D.C. Cir. June 2, 1999) (per curiam) (describing the holding of *Gullo v. Veterans Coop. Housing Ass'n*, 269 F.2d 517 (D.C. Cir. 1959) (per curiam)); see *Amore v. Accore, S.A.*, 484 F. Supp. 2d 124, 129 (D.D.C. 2007); *Burlington Res. Oil & Gas Co. v. U.S. Dep't of the Interior*, 21 F. Supp. 2d 1, 4 n.4 (D.D.C. 1998) (both considering issue preclusion *sua sponte* because the doctrine "belongs to courts as well as to litigants," *Stanton*, 127 F.3d at 77).

The Court should do so here. There is no reason to allow Ms. Lewis to manufacture a second federal case on an issue that she has already won in litigation against the Secretary. When Ms. Lewis received her first judgment, the claim for which she seeks review here was pending before the Medicare Appeals Council. She could simply have asked the Council to recognize the judgment in her favor; if it did not do so, she could have raised a simple plea of *res judicata* in district court. Instead she did neither, accelerating this case to federal court and then attempting to evade the effect of the earlier judgment. The only possible explanation for this stratagem is that Ms. Lewis wishes to serve as a class representative. For the reasons explained below, class certification would be inappropriate even if Ms. Lewis is allowed to litigate her case on the merits once again. But her desire to represent a class does not provide independent grounds for her repetitious claim. Indeed, that argument gets the relationship between individual claims and class claims precisely backwards: a plaintiff can serve as class representative only where she has a "personal stake in the outcome of the lawsuit." *Campbell-Ewald Co. v. Gomez*, 136 S. Ct. 663, 669 (2016) (quotations omitted). Ms. Lewis no longer has anything at stake in the Court's resolution of the merits of this case.

“Preclusion doctrine provides ample means to dispose of repetitive suits like this one.” *McLaughlin*, 803 F.2d at 1201. As the Supreme Court has long held, “matters which were actually litigated and determined in the first proceeding” between two parties “cannot later be relitigated.” *Sunnen*, 333 U.S. at 598. And “[t]here is . . . an important judicial concern at stake” in the application of issue preclusion here. *National Treasury Employees Union*, 765 F.2d at 1177. Ms. Lewis has litigated this issue once already, and she has prevailed. She is therefore entitled to payment of her claim for benefits. But Ms. Lewis has no right to needlessly consume the resources of the federal courts—and the Secretary, as well—by demanding a second determination on the merits.

Rather than entertaining repetitious litigation, this Court should take judicial notice of her earlier case, enter judgment on *res judicata* grounds, and remand her claim to the Secretary for payment of benefits.

B. This Court lacks subject matter jurisdiction over Douglas Sargent’s claims, which should be dismissed.

As the Secretary has explained in his pending motion to dismiss, Mr. Sargent’s claims both fall short of the Medicare Act’s minimum amount in controversy for judicial review, and this Court therefore lacks jurisdiction over them. For the convenience of the Court, and because these arguments are also relevant to certain issues regarding class certification, the Secretary briefly restates them here.

After exhausting administrative remedies, a Medicare beneficiary is “entitled . . . to judicial review of the Secretary’s final decision,” but “judicial review shall not be available to the individual if the amount in controversy is less than” an inflation-indexed sum, which stood at \$1,600 when this suit was filed. 42 U.S.C. § 1395ff(b)(1)(A), (E)(i), (iii); *see* 83 Fed. Reg. at 47,620. Mr. Sargent seeks judicial review of two final decisions of the Secretary, each of which

Plaintiffs have failed to affirmatively demonstrate the superiority of class litigation, as required by Rule 23(b)(3)—and that failure is especially acute as to the potential class members who participate in the Medicare Advantage program.¹⁵

CONCLUSION

This Court should 1) dismiss Mr. Sargent's claims for lack of subject matter jurisdiction, 2) take judicial notice of the preclusive effect of Ms. Lewis's earlier judgment and enter judgment in her favor on the grounds of *res judicata*, and 3) deny the motion for class certification as moot. If the Court proceeds to the merits of the class certification motion, it should deny that motion for the reasons set forth above, chief among them plaintiffs' failure to establish numerosity as required by Rule 23(a)(1).

Respectfully submitted,

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¹⁵ In accordance with Local Civil Rule 23(c), the Secretary respectfully suggests that the Court should "postpone a determination of the matter" of "how, when, by whom, and to whom the notice required by Fed. R. Civ. P. 23(c)(2) shall be given" until after the motion for class certification is decided, as the appropriate method of notice is likely to depend on the size of any class that may be certified. In addition, if the Court grants class certification, the Secretary suggests that it do so in general terms, and allow the parties to address the technical details of the class composition (which billing codes indicate class membership, for example) in any post-certification briefing.

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Date: April 21, 2020

Counsel for Defendant

EXHIBIT K

A

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TREATISE

ON THE

LAW OF ESTOPPEL

OR OF

INCONTESTABLE RIGHTS

BY

MELVILLE M. ^{edison} BIGELOW

SIXTH EDITION, REVISED

By JAMES N. CARTER, PH. B., J. M.

BOSTON

LITTLE, BROWN, AND COMPANY

1913

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B

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1892

ties when coming incidentally in question in another court for a different purpose. Having stated that the Spiritual Court had exclusive jurisdiction of questions of marriage, though the temporal courts entertained such questions incidentally, and that the latter courts were bound by the adjudications of the former courts between the same parties, he then said that the case was different when the judgments of the Spiritual Court were involved in *criminal* cases; for then the parties were in all cases different. The king, he said, in whom the trust of prosecuting public offences was vested, was no party to proceedings in the Ecclesiastical Court, and could not be admitted to defend, examine witnesses, intervene in any way, or appeal. He then proceeded to say that whatever might be the doctrine in regard to the conclusiveness of a positive adjudication concerning marriage when involved in a criminal case, a cause of jactitation was different.¹

Outram *v.* Morewood² is a leading case of high authority upon this subject.³ The case was this: An action of trespass

'This,' he said, 'is ranked as a cause of defamation only, and not as a matrimonial cause, unless where the defendant pleads a marriage; and whether it continues a matrimonial cause throughout, as some say, or ceases to be so on failure of proving a marriage, as others have said, still the sentence has only a negative and qualified effect; viz. that the party has failed in his proof, and that the libellant is free from all matrimonial contract, as far as yet appears; leaving it open to new proofs of the same marriage in the same cause, or to any proofs of that or any other marriage in another cause; and if such sentence is no plea to a new suit there . . . it cannot conclude a court which receives the sentence from going into new proofs to make out that or any other marriage. So that, admitting the sentence in its full extent and import, it only proves that it did not yet appear that they were married,

and not that they were not married at all; and by the rule laid down by Holt, L. C. J. such sentence can be no proof of anything to be inferred by argument from it; and therefore it is not to be inferred that there was no marriage at any time or place because the court had not then sufficient evidence to prove a marriage at a particular time and place. That sentence and this judgment may stand well together, and both propositions be equally true; it may be true that the Spiritual Court had not then sufficient proof of the marriage specified, and that your lordships may now, unfortunately, find sufficient proof of some marriage.' See *Hughes v. Jones*, 116 N. Y. 67, 22 N. E. 446, 15 A. S. R. 386.

² 3 East, 346. See *Loan Association v. Black*, 119 N. C. 323, 25 S. E. 975.

³ See among many other cases so treating *Outram v. Morewood*, *Pittapur v. Garu*, L. R. 12 Ind.

was brought for digging and getting out coals from a mine alleged by the plaintiff to be within and under his close, called Cowclose. The defendants pleaded and showed title by a regular chain in right of the wife from Sir John Zouch; and they averred that the coals in question were under the lands of Zouch, and were derived by bargain and sale to certain immediate bargainees, from them to the defendant, the wife, and were not within a certain exception named. To this plea the plaintiff replied, and relied by way of estoppel upon a former verdict obtained by him in an action of trespass brought by him against one of the defendants, the wife of the other defendant (she being then sole), in which he declared for the same trespass as now; to which the wife pleaded and derived title in the same manner as now by her and her husband, and in which she alleged that the coal mines in question in the declaration mentioned were at the time of making the above-mentioned bargain and sale by Zouch part and parcel of the coal mines by that indenture bargained and sold. And that upon this point, whether the coal mines claimed by the plaintiff and mentioned in his declaration were parcel of what passed under Zouch's bargain and sale to the persons under whom the wife claimed, an issue was taken and found for the plaintiff, and against the wife. The question was, in the language of Lord Ellenborough, 'whether the defendants, the husband and wife, were estopped by this verdict and judgment thereupon from now averring (contrary to the title so then found against the wife) that the coal mines now in question are parcel of the coal mines bargained and sold by the indenture above mentioned.' And it was held that they were.¹

App. 16; *De Mora v. Concha*, 29 Ch. D. 268, C. A. (affirmed on appeal nom. *Concha v. Concha*, 11 App. Cas. 541).

¹ In delivering the judgment of the court, Lord Ellenborough, C. J. said: 'The operation and effect of this finding, if it operate at all as a conclusive bar, must be by way of estoppel. If the wife were bound by this finding as an estoppel, and precluded from averring the contrary of what has been so found, the husband in respect of his

privity, either in estate or in law, would be equally bound. Coke, Litt. 352 a. [See *Lindsey v. Danville*, 46 Vt. 144, 148.] . . . The question then is, Is the wife herself estopped by this former finding? In *Brooke*, tit. Estoppel, pl. 15; *ibid.* Estate, 158, it is said to be "agreed that all the records in which the freehold comes in debate shall be estopped with the land, and run with the land; so that a man may plead this as a party, or as heir, as privy, or by que estate."

EXHIBIT L

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In re LCD Complaint:
Tumor Treatment Field Therapy
LCD ID Number: L34823
Contractor: CGS Administrators, LLC

Docket No. C-19-396

Date: May 28, 2019

**ORDER REGARDING DISCOVERY AND
ADDITIONAL EVIDENCE**

On May 20, 2019, CGS Administrators, LLC (CGS) filed its “Contractor’s Response to the Aggrieved Party’s Statement Regarding the LCD Record, Motion to Strike the LCD as Invalid, and Motion to Supplement Complaint (CGS response). Under the regulations, the next step is for me to evaluate the evidence that has been submitted and determine if “the LCD record is complete and adequate to support the validity of the LCD” under the reasonableness standard. 42 C.F.R. § 426.425(c)(1). For the reasons stated below, I conclude that the record presently is insufficient to support the validity of the challenged provision in LCD L34823. As a result, I order the parties to indicate whether they want me to close the record in this case or whether they want to engage in discovery or otherwise provide me with additional evidence. 42 C.F.R. § 426.425(c)(3).

I. The LCD’s record does not support the LCD’s validity.

After I accepted the Aggrieved Party’s Complaint in this matter, in conformance with the regulations governing this case, I ordered CGS to file the LCD record, the Aggrieved Party to file a statement explaining why the LCD is not valid, and CGS to file a response defending the LCD. *See* 42 C.F.R. §§ 426.410(d)(3), 426.425(a)-(b). The parties have completed their submissions. I have reviewed the submissions and conclude that the LCD record is insufficient to support the LCD’s categorical denial of coverage for tumor treatment field therapy (E0766) (TTFT).

A. The Aggrieved Party has standing to challenge the LCD.

CGS indicated that the Aggrieved Party's "LCD complaint is inapplicable as binding to the [Medicare Advantage] Plan" because Medicare Advantage Plans "have the option of providing individualized care if desired . . . and thus, are not bound to cover only Medicare-covered services." CGS Response at 1. Although not entirely clear, CGS appears to be challenging the Aggrieved Party's standing to challenge the LCD.

If this is the case, CGS is mistaken in its argument because an "Aggrieved party" includes enrollees in Medicare managed care plans so long as coverage for a service was denied based on the challenged LCD. 42 C.F.R. § 426.110. The Aggrieved Party meets these requirements. A. Ex. 8 at 5-6. Therefore, the Aggrieved Party has standing to challenge the LCD. 42 C.F.R. § 426.320(a).

B. An Aggrieved Party may challenge an LCD because it is outdated.

CGS asserted that the LCD record shows that the LCD was valid at the time the LCD was adopted. CGS further indicated that there is a reconsideration process for revising LCDs in the Medicare Program Integrity Manual, Chapter 13. CGS then concluded that "[n]either the relevant Statutes, Federal rules and regulations, nor sub-regulatory guidance issued by [the Centers for Medicare & Medicaid Services (CMS)] contemplated the role of an LCD Challenge as an alternate pathway for an LCD Reconsideration." CGS Response at 3-4, 7.

CGS misunderstands both the LCD challenge process and how it relates to the LCD reconsideration process. Congress established LCDs and provided some basic requirements related to the development of LCDs. 42 U.S.C. § 1862(l)(5). However, Congress also established an LCD review process, to be conducted by an administrative law judge (ALJ). 42 U.S.C. § 1395ff(f)(2). This process is meant to determine the validity of the LCD. *Id.* § 1395ff(f)(2)(i)(I). In promulgating the regulations to implement this process to challenge an LCD, the Secretary of Health and Human Services (Secretary) made it clear that the process for challenging the validity of an LCD may be invoked because "a challenger may believe that a policy that was correct when it was issued has become outdated and is no longer valid in light of advances in medicine." 68 Fed. Reg. 63,692, 63,700 (Nov. 7, 2003). In fact, the Secretary expressly permitted aggrieved parties to submit new evidence concerning the LCD so that the ongoing validity of the LCD could be tested. *Id.*; *see also* 42 C.F.R. § 426.403.

Further, the Secretary was fully aware of the LCD reconsideration process and provided procedures by which the contractor or the ALJ could evaluate whether new evidence submitted in the case warranted a reconsideration of the LCD. 42 C.F.R. §§ 426.340, 426.417. As stated in the preamble to the final rule:

We have modified the procedures at § 426.340 to allow the ALJ/Board to make a preliminary determination on whether the new evidence submitted would have a significant bearing on the validity of the LCD/NCD. If the evidence is found significant, it would be sent to the contractor/CMS to determine whether the contractor/CMS agrees that the evidence warrants a formal reconsideration. As mentioned earlier, the reconsideration process would be time limited but would allow the public to submit medical and scientific evidence and allow the agency to fully develop the record in light of advances in medical science. Following the time-limited reconsideration, a supplemental record would be filed and the adjudication could continue, if necessary.

This approach will provide the contractor/CMS the initial opportunity to permit medical and scientific experts to examine the new evidence and to make findings of fact concerning the new evidence. Among other things, the statute requires that the ALJ/Board “shall defer only to the reasonable findings of fact” and it was impossible for the agency to have made findings on evidence that did not yet exist or that had not been furnished to the agency for consideration. We believe this approach is necessary to ensure that the medical and scientific opinions of the agency experts illuminate the record, since these appeals could involve very technical medical and scientific material related to the new evidence.

68 Fed. Reg. at 63,700. The Secretary knew that the LCD review process and reconsideration processes are different. The preamble to the final rule stated:

5. Differences Between an LCD/NCD Review and an LCD/NCD Reconsideration

The main difference between an LCD/NCD review under section 522 of the BIPA and an LCD/NCD reconsideration is the avenue an individual chooses to take to initiate a change to a coverage policy and who may initiate the review. All interested parties, including an aggrieved party, may request a reconsideration of an LCD or NCD, rather than filing a complaint to initiate the review of an LCD or NCD. Conversely, only an aggrieved party may file a complaint to initiate the review of an LCD or NCD. If the aggrieved party

believes that we, or the contractor, misinterpreted evidence or excluded available evidence in making the coverage determination or has new evidence to submit, then the aggrieved party has the option to file a request for a reconsideration by the contractor or us, respectively, or to file a complaint to seek review by an adjudicator.

In the reconsideration process, all interested parties, not just aggrieved parties, have the opportunity to submit new scientific and medical evidence for review by individuals with medical and scientific expertise. The reconsideration process permits experts to make judgments about those policies, rather than using an adjudicatory proceeding.

68 Fed. Reg. at 63,694. Another major distinction between the LCD review process before an ALJ and the reconsideration process before a contractor is that an ALJ can only decide that an LCD provision is no longer valid, but cannot revise the LCD provision. 42 C.F.R. §§ 426.405(d)(14), 426.450(a)(2).

C. The LCD's record is inadequate to support the validity of the LCD.

CGS filed the record of the LCD in this case. The LCD was published in 2015, and the entire LCD record consists of documentation and reports from that time and earlier. However, the Aggrieved Party has submitted many documents and reports that more recently show the efficacy of TTFT, at least within certain parameters. Significantly, the Aggrieved Party has submitted 21 out of the 29 reports and journal articles that CGS has considered in the reconsideration process that CGS has already started. A. Exs. 5-6, 12, 70-72, 82, 95, 122-123, 125, 129, 136-137, 139, 143, 146, 150, 155, 157, 158; CMS Ex. 43 at 10-13. Further, based on these documents, CGS, along with other Medicare contractors, have proposed to remove the categorical prohibition on coverage of TTFT to permit coverage if specific criteria are met. CMS Ex. 44.

II. The parties may request to engage in discovery and submit additional evidence.

The regulations state:

If the ALJ determines that the LCD record is not complete and adequate to support the validity of the LCD, the ALJ permits discovery and the taking of evidence in accordance with §§426.432 and 426.440 and evaluates the LCD in accordance with §426.431.

42 C.F.R. § 426.425(c)(3).

In the present case, the Aggrieved Party appears likely to have submitted all of the evidence it plans to submit and CGS has already indicated that it neither plans to submit written direct testimony for any witnesses nor cross-examine the Aggrieved Party's witnesses. However, the parties will indicate by **June 5, 2019**, if they want to pursue discovery or to submit additional evidence.

Further, if the parties have objections to any of the exhibits submitted thus far by the other party, written objections must be submitted by **June 5, 2019**.

When the evidentiary record closes in this case, I will next need to determine whether the new evidence in the record is significant and permit CGS an opportunity to conduct a reconsideration. 42 C.F.R. § 426.340.



Scott Anderson
Administrative Law Judge

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EXHIBIT M



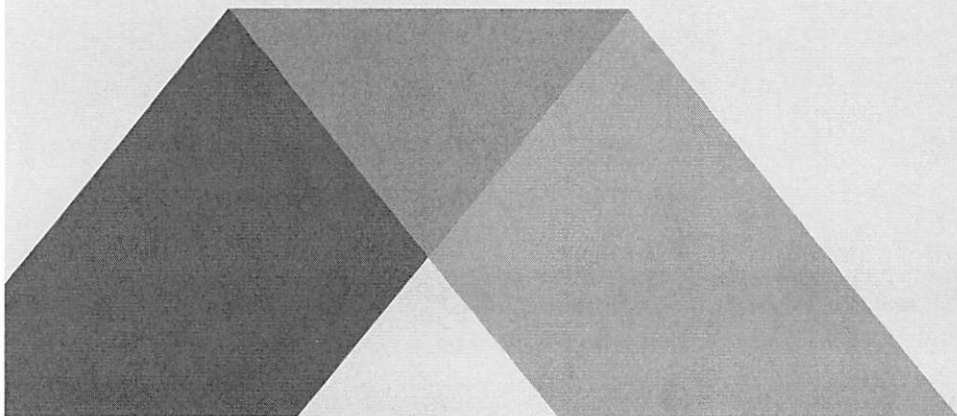
Financial Report

Fiscal Year **2018**

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AT A GLANCE

The Centers for Medicare & Medicaid Services (CMS) is an operating division within the Department of Health and Human Services (HHS). The CMS Annual Financial Report for FY 2018 presents the agency's detailed financial information relative to our mission and the stewardship of those resources entrusted to us. This report is organized into the following three sections:



MANAGEMENT'S DISCUSSION & ANALYSIS

This section gives an overview of our organization, programs, performance goals, and overview of financial data.



FINANCIAL SECTION

This section contains the message from our Chief Financial Officer, financial statements and notes, required supplementary information, and audit reports.



OTHER INFORMATION

This section includes the Summary of the Federal Managers' Financial Integrity Act Report and the Office of Management and Budget (OMB) Circular A-123—Management Responsibility for Enterprise Risk Management and Internal Control.

2018 FEDERAL OUTLAYS

CMS has outlays of approximately \$995 billion (net of offsetting receipts and Payments of the Health Care Trust Funds) in fiscal year (FY) 2018, approximately 16 percent of total Federal outlays.

CMS employs approximately 6,200 Federal employees, but does most of its work through third parties. CMS and its contractors process over one billion Medicare claims annually, monitor quality of care, provide the states with matching funds for Medicaid benefits, and develop policies and procedures designed to give the best possible service to beneficiaries. CMS also assures the safety and quality of medical facilities, provides health insurance protection to workers changing jobs, and maintains the largest collection of health care data in the United States (U.S.).

2018 PROGRAM ENROLLMENT

CMS is one of the largest purchasers of health care in the world. Medicare, Medicaid, and Children's Health Insurance Program (CHIP) provide health care for one in four Americans. Medicare enrollment has increased from 19 million beneficiaries in 1966 to approximately 59 million beneficiaries. Medicaid enrollment has increased from 11 million beneficiaries in 1966 to about 73 million beneficiaries.

